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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,622	09/30/2003	Nataragan Ranganathan	KBI-0017	7942

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Jane Massey Licata
Licata & Tyrrell P.C.
66 E. Main Street
Marlton, NJ 08053

EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/676,622

Applicant(s)

RANGANATHAN, NATARAGAN

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
4a) Of the above claim(s) 4-7 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/03/2005
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 – 3 in the reply filed on February 2, 2005 is acknowledged. The traversal is on the grounds that the searches are coextensive and that the search for the composition would inherently reveal references teaching the compositions useful for the claimed methods. Applicant additionally argues that the inventions are not independent and distinct. This is not found persuasive because as stated previously and reiterated, the inventions are distinct in that the method could be practiced by administering other materially different products such as fruit juice while the compositions of bacteria could be used in other materially different methods such as denitrifying water systems (as evidenced by US 6025152). As such, while the search for the two groups may indeed overlap, the searches are not coextensive. Thus a reference for one group would not necessarily anticipate or even make obvious the other.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4 – 7 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1 – 3 have been considered on the merits.

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Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2 – 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rendered vague and indefinite for reciting “B. pasteurii” because the claim should first spell the genus before abbreviating.

Claim 3 is rendered vague and indefinite for reciting “L. sporogenes” because the claim should first spell the genus before abbreviating.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 1 – 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Hiatt (US 6025152 A).

Applicant claims a composition for treating renal failure comprising a selected bacteria which converts nitrogenous wastes into non-toxic compounds in vivo. The bacteria is *B. pasteurii* or *L. sporogenes*.

Hiatt teaches compositions comprising bacteria which convert nitrogenous waste to non-toxic compounds (Col.2 line 50-60) wherein the bacteria are *B. coagulans* (or *L. sporogenes*) and/or *B. pasteurii* (col.3 line 5-12,20-25, col.4 line 25-30).

Although the reference does not teach the composition is used for treating renal failure, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Moreover, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112) Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Therefore, the reference anticipates the claimed subject matter.

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6. Claims 2 – 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiatt.

Applicant claims a composition for treating renal failure comprising a selected bacteria which converts nitrogenous wastes into non-toxic compounds in vivo wherein the bacteria is *B. pasteurii* or *L. sporogenes*.

Hiatt teaches compositions comprising bacteria which convert nitrogenous wastes to non-toxic compounds (Col.2 line 50-60) wherein the bacteria are *B. coagulans* (or *L. sporogenes*) and/or *B. pasteurii* (col.3 line 5-12,20-25, col.4 line 25-30).

Although the reference does not teach the composition is used for treating renal failure, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Moreover, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112) Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Therefore, the reference anticipates the claimed subject matter.

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7. Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Reddy et al. (6080401A).

Applicant claims a composition for treating renal failure comprising a selected bacteria which converts nitrogenous wastes into non-toxic compounds in vivo wherein the bacteria *L. sporogenes*.

Reddy teaches compositions comprising probiotics wherein the bacteria is *L. sporogenes* (abstract, col.4 line 60-65, col.9 – 10, examples).

Although the reference does not teach the composition is used for treating renal failure, or that the bacteria converts nitrogenous wastes into non-toxic compounds in vivo, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. In addition, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112) Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

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Therefore, the reference anticipates the claimed subject matter.

8. Claim 3 is rejected under 35 U.S.C. 102(a) as being anticipated by Reddy.

Applicant claims a composition for treating renal failure comprising a selected bacteria which converts nitrogenous wastes into non-toxic compounds in vivo wherein the bacteria *L. sporogenes*.

Reddy teaches compositions comprising probiotics wherein the bacteria is *L. sporogenes* (abstract, col.4 line 60-65, col.9 – 10, examples).

Although the reference does not teach the composition is used for treating renal failure, or that the bacteria converts nitrogenous wastes into non-toxic compounds in vivo, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. In addition, the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112) Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

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Therefore, the reference anticipates the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
April 6, 2005
AU 1651

A handwritten signature in black ink, appearing to read 'R. Davis', is written over the typed name and date.